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| APPLICATION NO.                  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|----------------------------------|-------------|----------------------|---------------------|------------------|
| 10/748,135                       | 12/31/2003  | Steven Bernard       | 3659-78             | 6862             |
| 23117                            | 7590        | 02/13/2006           | EXAMINER            |                  |
| NIXON & VANDERHYE, PC            |             |                      | KIM, SUN U          |                  |
| 901 NORTH GLEBE ROAD, 11TH FLOOR |             |                      | ART UNIT            | PAPER NUMBER     |
| ARLINGTON, VA 22203              |             |                      | 1723                |                  |

DATE MAILED: 02/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                        |                     |
|------------------------------|------------------------|---------------------|
| <b>Office Action Summary</b> | <b>Application No.</b> | <b>Applicant(s)</b> |
|                              | 10/748,135             | BERNARD ET AL.      |
|                              | <b>Examiner</b>        | <b>Art Unit</b>     |
|                              | John Kim               | 1723                |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) Responsive to communication(s) filed on 31 December 2003.
- 2a) This action is FINAL.                            2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-15 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 31 December 2003 is/are: a) accepted or b) objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 4/23/04, 3/11/05.
- 4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: \_\_\_\_\_.

1. Figure 14 should be designated by a legend such as --Prior Art-- because only that which is old is illustrated. See MPEP § 608.02(g). Corrected drawings in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.
2. Claim 7 is objected to because of the following informalities: A semi-colon on line 4 after the first occurrence of "material" should be removed. Appropriate correction is required.
3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1-6 are rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling. A housing for containing the bundle of hollow fibers and a second filter header cap having an outlet and an open end sealed around a side surface of the opposite end section of the bundle of the hollow fibers are critical or essential to the practice of the invention, but not included in the claim(s) is not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976). Without a housing for containing the bundle of hollow fibers and a filter header cap having an outlet at the opposite end section of the bundle of hollow fibers, the claimed filter would not function as an intended filter for an extracorporeal blood circuit (see figures 2 and 4).

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5. Claims 7-15 are rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling. A second filter cap at the other end of the housing and a second filter header cap having an outlet and an open end sealed around a side of the stem at the opposite end section of the bundle of the hollow fibers are critical or essential to the practice of the invention, but not included in the claim(s) is not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976). Without a second filter cap at the other end of the housing and a second filter header cap having an outlet and an open end sealed around a side of the stem at the opposite end section of the bundle of the hollow fibers, the claimed filter would not function as an intended filter for an extracorporeal blood circuit (see figures 2 and 4).

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 3-4 and 8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 3-4 and 8 are indefinite for failing to particularly point out and distinctly claim that a rim of potting material having an average width of claimed range rather than fibers having an average width of claimed range as currently presented.

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this

subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

9. Claims 1-2 and 5-6 are rejected under 35 U.S.C. 102(b) as being anticipated by Spranger et al (US Pat. No. 4,990,251). Spranger et al teach a filter comprising a bundle of hollow fibers (1) arranged in a tubular housing (2) and having an end section encased in a potting material (3) and an end surface with open ends of the fibers throughout the end face and a filter header cap (14) having an inlet (15) connectable to a liquid line and an open end sealed around a side surface of the end section of the bundle of hollow fibers (1) (see figures 1-2; col. 4, line 65 – col. 5, line 34)(claim 1). Regarding claim 2, Spranger et al show that the inlet (15) is coaxial with the filter (see figure 1). Regarding claim 5, Spranger et al show that the end section is an end of a stem of the bundle extending outward and downwardly from a disk of the potting material (3) (see figure 1). Regarding claim 6, Spranger et al show that the disk of the potting material (3) is fitted into the cap (14) and the cap (14) is mounted on the cylindrical tube (2) housing the bundle (1) (see figure 1).

10. Claims 1-2 and 5-6 are rejected under 35 U.S.C. 102(e) as being anticipated by Patterson et al (US Pat. No. 6,387,324). Patterson et al teach a filter comprising a bundle of hollow fibers (70) arranged in a tubular housing (72) and having an end section encased in a potting material (78) and an end surface with open ends of the fibers throughout the end face and a filter header cap (74) having an inlet (88) connectable to a blood line and an open end sealed around a side surface of the end section of the bundle of hollow fibers (70) (see figure 3; col. 17, line 14 – col. 18, line 9)(claim 1). Regarding claim 2, Patterson et al show that the inlet (88) is coaxial with the filter (see figure 3). Regarding claim 5, Patterson et al show that the end section is an end of a stem of the bundle extending outward and upwardly from a disk of the potting material (78)

(see figure 3). Regarding claim 6, Patterson et al show that the disk of the potting material (78) is fitted into the cap (74) and the cap (74) is mounted on the cylindrical tube (72) housing the bundle (70) (see figure 3).

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. Claims 3-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Spranger et al. Spranger et al teach the filter as described in above paragraph 9. Spranger et al shows that rim area of the potting material (3) is devoid of the open ends of the fibers (see figure 1). Claims 3-4 essentially differ from the filter of Spranger et al in reciting that the end surface includes a rim area of potting material having a width no greater than on average than 0.508 mm. The rim area of the potting material of Spranger et al provides a wall surrounding the bundle of hollow fibers fitted in a housing (2) (see figure 1; col. 5, lines 3-5). It would have been obvious to one having ordinary skill in the art at the time the invention was made to optimize the width of wall i.e. rim area of the potting material in the filter of Spranger et al to be supported in a housing (2), since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US Pat. No. 4,414,110 and 5,072,498 and 4,334,993 and US 2003/0029785 and US 2003/0010718 teach filter having hollow fiber bundles and a filter head cap.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to John Kim whose telephone number is (571) 272-1142. The examiner can normally be reached on weekdays from 8:30 A.M. to 5:00 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Wanda Walker, can be reached on (571) 272-1151. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



John Kim  
Primary Examiner  
Art Unit 1723

J. Kim  
February 8, 2006